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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,370	06/22/2001	Laurie H. Glimcher	HUI-027CPDV2	8885

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.	Applicant(s)
09/888,370	Glimcher et al.
Examiner	**Art Unit**
Joseph Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 3, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *27-38* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *27-38* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a divisional application of 09/086,010, filed May 27, 1998, now patent 6,274,338, which is a continuation in part of 09/030,579, filed February 24, 1998, now abandoned.

Applicants' amendment filed April 3, 2003, paper number 8, has been received and entered. Claims 33-38 have been added. Claims 27-38 are pending and currently under examination.

Election/Restriction

Applicant's election without traverse of group II, claim 28, in Paper No. 8, is acknowledged. In light of the addition of newly added claims 33-37, the previous restriction requirement has been withdrawn and a new restriction requirement is being made.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 27, drawn to a method of detecting the presence of human c-Maf in a biological sample, classified in class 530, subclass 387.1.

II. Claim 28, 33-38 drawn to a method for modulating human c-Maf activity in a cell, classified in class 435, subclass 325.

III. Claims 29, 30 and 32, drawn to method to identify a compound that modulates the activity of a human c-Maf protein comprising evaluating the binding of a human c-Maf and a DNA molecule, classified in class 435, subclass 6; class 435, subclass 7.1; class 435, subclass 325; class 435, subclass 69.1.

IV. Claims 29, 31 and 32, drawn to method to identify a compound that modulates the activity of a human c-Maf protein comprising evaluating the expression in an indicator cell, classified in class 435, subclass 6; class 435, subclass 7.1; class 435, subclass 325; class 435, subclass 69.1.

Claims 29 and 32 are generic to both groups III and IV and will be examined to the extent they encompass the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions I -IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different and separate methods requiring different method steps, and which result in the identification materially products. The method of group I requires a product which can be used to detect c-Maf protein, such as an antibody, the method of group II requires a specific compound which modulates the activity of c-Maf, and the both methods of groups III and IV require no knowledge of the compounds tested and are drawn generally to methods in which these compounds can be identified, however each groups uses a different indicator to test

the compounds. Thus, each group requires different starting materials and different method steps to practice. The compounds used for each method, i.e. detecting, modulating and testing are not co-extensive in activities and would require a separate search and consideration. Further, each method results in a materially different outcome when practiced.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In addition, this application contains claims directed to the following patentably distinct species of the claimed invention: The methods of group II are drawn to the analysis of different types of modulation: (1) inhibiting c-Maf activity (claim 33), and (2) stimulating c-Maf activity (claim 34). **Furthermore**, this application contains claims directed to the following patentably distinct species of the claimed invention: The methods of group II are drawn to analyzing different forms of modulation: including affecting modulation of: (1) the c-Maf polypeptide (claim 35), (2) the c-Maf gene (claim 36), and the c-Maf mRNA (claim 37). **Finally**, this application contains claims directed to the following patentably distinct species of the claimed invention: The methods of group II are drawn to the analysis of different types agents: (1) antisense nucleic acids, (2) antibodies, (3) dominant negative inhibitors, (4) c-Maf nucleic acids, and (5) chemicals (all in claim 38). Applicants are required to elect one from each of these three different patentably distinct groups of species listed above.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, because of the open language of "comprising" recited in the pending claims, claims 28 is generic to all the indicated species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In addition, this application contains claims directed to the following patentably distinct species of the claimed invention: The methods of group III are drawn to the use of different types of indicator complexes: (1) c-Maf protein by itself; (2) c-Maf protein and a DNA molecule to which c-Maf binds; and (3) a cell containing a reporter gene construct comprising a specific promoter sequence operatively linked to a reporter gene.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, because of the open language of "comprising" recited in the pending claims, claims 29 is generic to all the indicated species because of the presence of at least a c-Maf protein in the indicator complex.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

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